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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,232	02/02/2001	Thomas M. Kundig	CTLIMM.001CP2	8151

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EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,232

Applicant(s)

KUNDIG ET AL. *MT*

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-59^{60, 61} is/are pending in the application.
- 4a) Of the above claim(s) 52-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-51^{60, 61} is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/02/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 38-51, 60, and 61, drawn to a method of inducing a CTL response by delivering an antigen directly to a mammal's lymphatic system, classified in class 604, subclass 500.
- II. Claims 52-59, drawn to a method of inducing a CTL response by delivering an antigen by pumping a composition from an external device, classified in class 604, subclass 508.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as not requiring an external pump, but requiring direct delivery to the lymphatic system. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Marc Morley on 1/25/02 a provisional election was made without traverse to prosecute the invention of group I, claims 38-51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 52-59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

IDS

No copies of the references listed on the IDS, Paper No. 3, received 5/7/01 were submitted in the present application because they were submitted in the parent application 09/380534. The examiner has not been able to locate the previously submitted references. While the US patents were able to be reviewed after entering the patent numbers in the USPTO database, the foreign patent documents and other documents could not be retrieved. The examiner requests Applicant to resubmit the references cited as foreign patent documents and other documents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 40, 41, 43, 45, 48, 49, 50, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by FELGNER et al. (U. S. Patent No. 5,589,466). Felgner (col. 5, line 39 - col. 8,

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line 10) discloses a method of inducing and maintaining a CTL response in a mammal including delivering an antigen in the form of a nucleic acid encoding the antigen directly to the lymphatic system (i.e., spleen, 7:1-4).

Claims 38, 40, 41, 43, 45, 46, 48, 49, 50, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by CARSON et al. (U. S. Patent No. 5,679,647). Carson discloses delivering a nucleic acid encoding an antigen to antigen presenting cells (veiled cells of afferent lymphatics and interdigitating cells of lymphoid organs, 5:56-59).

Claims 38, 40, 41, 43, 45, 46, 48, 49, 50, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by KUBO et al. (U. S. Patent No. 6,037,135). Kubo discloses delivering a nucleic acid encoding an antigen to lymphoid tissue via liposomes. (15:45-59).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38, 39, 40, 41, 42, 45, 46, 47, 49, 50, 51, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over VITIELLO et al. (U. S. Patent No. 6,419,931 B1) in view of KUNDIG (Science, Vol. 268, 2 June 1995). Vitiello discloses a method of inducing and maintaining a CTL response in a mammal including delivering an antigen; viral, bacterial, parasitic, or tumor antigen to a patient. Vitiello does not disclose administering the antigen directly to the lymphatic system. Kundig teaches the step of delivering antigen directly to the

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lymphatic system because: "Antigens outside of lymphoid organs are ignored by T cells, whereas antigens newly transported into lymphoid organs provoke a response." (pg. 1346). Kundig teaches delivery directly to the lymphatic system to make use of the cytokine-rich environment of the lymphoid organs (pg. 1346). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kundig in the method of Vitello in order to efficiently elicit a CTL response. The use of a pump to deliver therapeutic liquid is notoriously well known in the art.

Claims 38-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over BOT et al. (U. S. Patent No. 6204250 B1) in view of KUNDIG (Science, Vol. 268, 2 June 1995). Bot (col. 2, lines 29-64) discloses a method of inducing and maintaining a CTL response in a mammal including delivering an antigen in the form of a nucleic acid encoding the antigen. Bot does not disclose administering the antigen directly to the lymphatic system. Kundig teaches the step of delivering antigen directly to the lymphatic system because: "Antigens outside of lymphoid organs are ignored by T cells, whereas antigens newly transported into lymphoid organs provoke a response." (pg. 1346). Kundig delivers directly to the lymphatic system to make use of the cytokine-rich environment of the lymphoid organs (pg 1346). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kundig in the method of Bot in order to efficiently elicit a CTL response. Re claim 44 the use of the claimed carrier for the antigen is well known in the art. The use of a pump to deliver therapeutic liquid is notoriously well known in the art.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday-Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be reached at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The number for submitting after final papers is (703) 872-9303.



MICHAEL J. HAYES
PRIMARY EXAMINER